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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,245	06/07/2005	David Feifel	034123-122	3580
41790	7590	07/03/2007		
BUCHANAN, INGERSOLL & ROONEY LLP			EXAMINER	
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			ART UNIT	PAPER NUMBER
			1649	
			MAIL DATE	DELIVERY MODE
			07/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,245	Applicant(s) FEIFEL, DAVID	
	Examiner Aditi Dutt	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,15-19,21-27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-10,19 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18,21-26 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10,15-19,21-27 and 29-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Status of Claims

1. The amendment filed on 28 March 2007 has been entered in full. Claims 15-18, 24-26 and 31-32 have been amended. Claims 20 and 28, are canceled.
2. Claims 1-10, 15-19, 21-27, and 29-34 are pending in the instant application. Claims 15-18, 21-26, 29-34, drawn to a method for increasing sensorimotor gating or inhibiting serotonin-2A and/or alpha-1 receptor mediated neural function and improving cognitive function by administration of neurotensin agonist to a subject, are being considered for examination in the instant application, are under examination in the instant office action.
3. The text of any section of 35 U.S.C. not reiterated in this office action can be found in a previous office action.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants response and withdrawn.
5. Applicant's arguments filed on 28 March 2007, have been fully considered. New grounds of objection and rejection are as follow.

Response to Amendment

Withdrawn objections and/or rejections

6. Upon consideration of the amendment of independent claim to recite the elected neurotensin agonist NT69L, rejection of the claims 15-18, 24-26 and 31 under 35 USC § 102(b) is withdrawn.
7. Upon consideration of the amendment and cancellation of relevant claims, rejection of the claims 15-18, 20-26 and 28-30, under 35 USC § 112, second paragraph is withdrawn.

Claim rejections/objections maintained/new grounds of rejection

35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 15-16, 21-23, 29-34 are being applied to the amended claims 15-18, 21-26 and 29-34, for reasons of record in the Office Action dated 28 December 2006 (pages 5-10).
9. Applicant argues that since an animal model characterized as having reduced pre-pulse inhibition (PPI) is used as a working example in the instant application, and because reduced PPI is recognized as being present in neuropsychiatric disorders, the method of treating such disorders, like

schizophrenia would "bear a reasonable correlation to the claimed subject matter and support in the specification". Applicant further objects to the citation of Ni et al., on grounds that the "genetic susceptibility to bipolar disorders" stated by Ni et al. is not within the scope of the claimed invention. Applicant, therefore, requests the withdrawal of the rejection.

10. Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the previous Office Action (para 21), it is reiterated:

....because of the "heterogeneous etiologies involving complex interactions among genetic and environmental factors" and because of the involvement of multiple brain functions in the behavioral states in diseases such as schizophrenia, and bipolar disorders, the lack of a valid animal model is a major limitation (Kilts. Biol Psychiatry 50: 845-855, 2001, page 846, column 1, para 1; Einat, J Psycopharmacol 20: 714-722, 2006). As a cautionary note, the art suggests that PPI is only one factor of the disease pathology of various neuropsychiatric illnesses, and "although an induced deficit in PPI in adult rats may have valid relationship to key psychophysiologic impairments related to schizophrenia", and bipolar disorder, "it might bear no relationship to the pathogenesis of the disorder" (Kilts, page 852, concluding para). Finally, it is well known in the art and further reiterated in the instant specification that "many patients with schizophrenia and other neuropsychiatric illnesses are considered "treatment refractory" (page 10, para 0032):

Furthermore, as stated earlier, PPI of the acoustic startle response depended on the state of the bipolar disorder in the patient, PPI levels being normal in the euthymic state. The state of the art is further summarized by Caceda et al., (Peptides 27: 2385-2404, 2006; page 2388, Section 5), that states "the current pharmacologic treatment of schizophrenia is still far from ideal". Additionally, Applicant's argument about the misplacement of the Ni et al. reference is not persuasive, as the arguments presented in the Office Action were meant to state

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that serotonin 2A is not quite involved in the etiology of bipolar disease, based on the statement that serotonin 2A receptor gene 'does not play a role in the genetic susceptibility of the disease'. Examiner did not intend to focus Applicant's attention to the gene expression of serotonin 2A receptor.

11. Specifically, proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to increase sensorimotor gating in a subject having any neuropsychiatric disorder by administering NT69L and thereby improving cognitive function and memory; lack of direction/guidance presented in the specification regarding the same; the complex nature of the invention; the absence of an appropriate animal model for bipolar disorder; the state of the prior and post art which has yet to determine clear nexus between all states of bipolar disorder, NT and PPI and, the unpredictability of treatment of neuropsychiatric diseases; undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

New Rejection

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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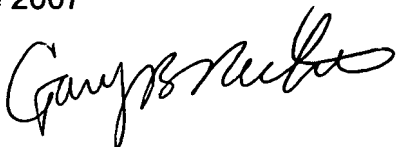
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 15-18, 22, 24-26 and 31, are rejected under 102(a) as clearly anticipated by Hedley et al (Soc for Neurosc Meet Abs, August 2002).
14. The claims are directed to a method for modulating sensorimotor gating in a subject having inherently reduced PPI, or any neuropsychiatric disorder associated with sensorimotor gating abnormalities, causing a decrease in PPI by administering a neurotensin agonist, NT69L, in combination with other psychiatric drugs to increase PPI (claims 15-18, 22). The claims further recite the inhibition of serotonin receptor mediated neural function, or improving cognitive function and/or memory attention by administration of NT69L in a subject (claims 24-26, 31).
15. Hedley et al. teach that the intraperitoneal (parenteral) injection of NT69L to male mice and rats resulted in a reversal of PPI reduction produced by the glutamate antagonist dizocilpine. Since the instant specification teaches that reduced PPI of the acoustic startle response is a symptom that is inherently an abnormality of sensorimotor gating (page 2, para 0005-0006), and further teaches that serotonin-2A receptor agonists inherently induce reduced PPI, similar to that observed in schizophrenia (page 8, para 0028), the limitations of the claimed inventions are inherent. Because the method steps disclosed by Hedley et al. meet the limitations of claims 15-18, 24-26, and 31 of the instant application, the reference anticipates the claimed invention.

Conclusion

16. No claims are allowed.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.
18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
16 June 2007



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